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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/597,580 | 06/20/2000 | Gary L. Griffiths | 018733/0987 | 5842 |

7590

01/11/2002

Law Offices
Foley & Lardner
3000 K Street NW Suite 500
Washington, DC 20007-5109

| EXAMINER |
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JONES, DAMERON LEVEST

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1619

DATE MAILED: 01/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/597,580

Applicant(s)

GRIFFITHS ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2000 and 16 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42,44 and 46-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42,50 and 51 is/are rejected.
- 7) ☒ Claim(s) 44,46-49 and 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

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ACKNOWLEDGMENTS

1. The Examiner acknowledges Paper No. 8, filed 11/16/01, wherein claims 43 and 45 were canceled; claim 1 was amended; and claims 46-52 were added.

Note: Claims 1-42, 44, and 46-52 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to therapeutic compositions having the components as set forth in independent claims 1, 37, and 38.

ELECTION OF SPECIES

3. Applicant's election of a first conjugate that binds hapten and comprises doxorubicin and a second conjugate comprising a hapten that carries topotecan as the second therapeutic agent in Paper No. 8, filed 11/16/01, is acknowledged. However, since prior art could not be found to reject Applicant's elected species, the search was expanded to encompass the full scope of the instant invention.

DOUBLE PATENTING

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-42, 44, and 46-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 09/597,580. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention encompasses the claims of the patented invention.

In particular, independent claims 1, 24, 33, and 36 of the patented invention differs from that of the instant invention in that the (1) claim 1 of the patented invention contains additional components when compared to broad claim 1 of the instant invention; (2) claim 37 of the instant invention sets forth specific first therapeutic agents; and (3) claim 38 of the instant invention contains binding pairs selected from a

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complementary DNA fragment, complementary peptide oligonucleotides, and corresponding enzymes and prodrugs.

112 REJECTIONS

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11, 14, 21, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 14: The claims as written are ambiguous because it is unclear what is intended by the phrases 'ethylenimine derivatives', 'folic acid analogs', 'pyrimidine analogs', 'purine analogs', and 'methyl hydrazine derivatives'. In particular, it is unclear which portion of the original structure remains. Likewise, it is unclear what 'antagonists' and 'hormones' Applicant is referring to. Is Applicant saying that all antagonists and hormones may be used with the instant invention?

Claims 21 and 26: Applicant is reminded that the recitation that an element is 'capable of' performing a function is not a positive limitation, but only requires the ability to so perform that function. Thus, the use of such terminology does not constitute a limitation in any patentable sense (In re Hutchison, 69 USPQ 138). Hence, it is unclear whether Applicant intended to replace 'capable of specifically binding' with 'binds'.

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CLAIM OBJECTIONS

8. Claims 44, 46-49, and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

COMMENTS/NOTES

9. Claims 1-42, 44, and 46-52 are allowable over the prior art of record; however, Applicant must address and overcome the double patenting and 112, second paragraph, rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious compositions as set forth in independent claims 1, 37, and 38. The closest art is Applicant's own work cited in the double patenting rejection above.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'D. L. Jones', with a stylized, cursive script.

D. L. Jones
Primary Examiner
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January 4, 2002